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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,348	02/14/2002	Jotham Wadsworth	PC10030D	9919

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,348	WADSWORTH ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10 and 15-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10 and 15-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 1-6, 8, 10 and 15-35 are pending in the application.

This action is in response to applicants' amendment filed July 12, 2004.

Claims 1, 25 and 26 have been amended.

Response to Arguments

Applicants' arguments filed July 12, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that the specific compounds that are embraced by the cited classes are common knowledge to those skilled in the art. However, the additional active ingredient within the terms a **muscarinic agonist**, a **neurotrophic factor**, an **agent that slows or arrests Alzheimer's disease**, an **amyloid aggregation inhibitor**, a **secretase inhibitor**, a **tau kinase inhibitor**, a **neuronal anitainflammatory agent** and an **estrogen-like therapeutic agent** is not defined in the specification. The terms are of indeterminate scope.

It is the Wands factors, which are used to evaluate the enablement question. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the instant invention, has claims which embrace substituted 10-aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-triene compounds. The instant compounds of formula (I) wherein the additional active ingredients are not described in the disclosure in such a way the one of ordinary skill in the art would no how to prepare the various compounds suggested by claims 1-6, 8, 10 and 15-35. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention.

Claims 1-6, 8, 10 and 15-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 15 and 16, labeled paragraph 3) of the last office action, which are hereby **withdrawn**.

3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 4) of the last office action, which are hereby **withdrawn**.

4. With regards to the obviousness-type double patenting rejection of claims 1-6, 8, 10, 15-19, 22, 24-27 and 30-35, labeled paragraph 5) in the last office action, the

applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that claims 1-6, 8, 10, 15-19, 22, 24-27 and 30-35, do not recite "an analgesic agent or pharmaceutically acceptable salt thereof" and are patentably distinct from claims 1-34 of copending Application No. 10/348,381.

However, the analgesic agents of 10/348,381 include opioid analgesics, NMDA antagonists, substance P antagonists, COX 1 and COX 2 inhibitors, tricyclic antidepressants (TCA), selective serotonin reuptake inhibitors, (SSRI), capsaicin receptor agonists, anesthetic agents, benzodiazepines, skeletal muscle relaxants, migraine therapeutic agents, anti-convulsants, anti-hypertensives, anti-arrhythmics, antihistamines, steroids, caffeine, N-type calcium channel antagonists and botulinum toxin of which some of these active ingredients can also be considered a muscarinic agonist, a neurotrophic factors, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal anti-inflammatory agent and an estrogen-like therapeutic agent. For example COX 2 inhibitors are known to be anti-inflammatory agents.

Claims 1-6, 8, 10, 15-19, 22, 24-27 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,381, for reasons of record and stated above.

5. With regards to the obviousness-type double patenting rejection of claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35, labeled paragraph 6) in the last office action, the applicants' amendments and remarks have been fully considered but they are not found

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persuasive. The applicants' stated that claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35, do not include an antidepressant while claims 1-18 of copending Application No. 10/348,399 recite pharmaceutical compositions and methods of use based on a combination of "a nicotine receptor partial agonist and an anti-depressant or anxiolytic agent". However, the anxiolytic agents of 10/348,399 include benzodiazepine (e.g. diazepam, alprazolam, chlordiazepoxide) or non-benzodiazepine anxiolytics (e.g. buspirone, hydroxyzine, doxepin) in order to treat the anxiety associated with addiction such as to nicotine or tobacco, alcohol dependence, cocaine addiction or tobacco or nicotine dependence independently of other psychiatric illness of which some of these active ingredients can also be considered a muscarinic agonist, a neurotrophic factors, an agent that slows or arrests Alzheimer's disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, a neuronal anti-inflammatory agent and an estrogen-like therapeutic agent.

Claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,399, for reasons of record and stated above.

6. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection of claims 1, 3-6, 8, 10 and 15-26, labeled paragraph 7) in the last office action, which is hereby **withdrawn**.

7. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection of claims 1, 3, 8, 10 and 24-26, labeled paragraph 8) in the last office action, which is hereby **withdrawn**.

8. The applicants' amendments and arguments are sufficient to overcome the obviousness-type double patenting rejection of claims 1-6, 8, 10 and 24-35, labeled paragraph 9) in the last office action, which is hereby **withdrawn**.

In view of the amendment dated July 12, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 1, 8, 10 and 15-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim

indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 (and claims dependent thereon) recite the broad recitation "monocyclic and bicyclic rings may optionally be substituted with one or more substituents", and the claims also recite "preferably from zero to two substituents" which is the narrower statement of the range/limitation. See the first line of page 4 in the amendment filed July 12, 2004

b) Claim 15 recites the limitation "2-fluorobenzamide" in the first species.

There is insufficient antecedent basis for this limitation in the claim.

c) Claim 16 recites the limitation "acetamide" in the fourth species. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman

Primary Examiner Art Unit 1624

August 18, 2004